DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

95125d

December 8, 2004

Ref: 2005-DAL-WL-06

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Jennifer L. Sechrist, R.Ph./President
Veterinary Enterprises of Tomorrow, Inc.
225 Main Street
Mountain View, Oklahoma 73072

Dear Mrs. Sechrist:

An inspection of your veterinary drug compounding facility, located at 225 Main Street, Mountain View, Oklahoma, conducted by investigators of the Food and Drug Administration (FDA) between the dates of July 26-30, 2004, disclosed significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigators were accompanied by Ms. Cindy Hamilton, Senior Pharmacy Inspector with the Oklahoma Board of Pharmacy.

Our inspection confirmed that your company has compounded and distributed veterinary drugs, including Nitrofurazone, Chloramphenicol Palmitate, Enrofloxacin, Omeprazole, and Dipyrone, among many others, using bulk active pharmaceutical ingredients (bulk APIs). The veterinary drugs you are compounding are unsafe within the meaning of section 512 of the Act (21 U.S.C. § 360b) since they are not the subject of approved New Animal Drug Applications. As such, they are adulterated under section 501(a)(5) of the Act (21 U.S.C. § 351(a)(5)). Sections 512(a)(4) and (5) of the Act (21 U.S.C. 360b(a)(4) and (5)), and their implementing regulations, allow some extralabel use of approved animal and human drugs, including compounding from approved animal and human drugs. These provisions, however, apply only to approved drugs and do not permit compounding from bulk APIs (see Title 21, Code of Federal Regulations (CFR), 530.13(a)).

FDA's policy regarding the compounding of drugs for use in animals is articulated in Compliance Policy Guide, Section 608.400, issued July 2003. As stated in this policy, FDA is greatly concerned about veterinarians and pharmacies that manufacture and distribute unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act.

One of our concerns is that you are not compounding for individual patients, but are compounding for third parties, generally veterinary clinics, who resell to individual patients. A significant number of your compounded veterinary drugs appear to be compounded outside the context of a valid veterinarian-client-patient relationship for administration by an end user. Instead, there appear to be sales to veterinarians for use as office stock in their professional practice and/or for subsequent general distribution. For example, recent consignee information provided to investigators for each of the above listed drugs confirmed that these compounded drugs were shipped to veterinarians, and you reported that less than five percent of your product goes directly to the end user. In addition, your prescription drug labeling for clinic use does not identify the animals to receive treatment, provide the dosage frequency, or provide the duration of treatment.

Another concern is that you are compounding drugs for use when an approved drug, in the available dosage form and concentration, would appropriately treat the animal. For example, some of your compounded prescription veterinary drugs, such as Nitrofurazone .2% topical solution, are duplicates of FDA approved animal drug products available on the market. Others have only slightly different dosages and/or concentrations than FDA approved animal drugs, such as Enrofloxacin 136 mg capsules where Enrofloxacin 136 mg tablets are approved and available, and these differences appear to be clinically insignificant.

A third concern is that the drugs being compounded could be used in food producing animals and, therefore, could result in unsafe drug residues in edible tissues. For example, the prescriptions you receive and the labeling you generate often do not specify the target animal species. Moreover, at least three of the drugs being compounded, Nitrofurazone, Chloramphenicol, and Diethylstilbestrol, are not permitted for extralabel use in food producing animals because they present a risk to public health.

The above is not intended to be an all-inclusive list of violations by your firm. It is your responsibility to ensure that your firm's operations and products are in compliance with the law and applicable regulations. Our findings were listed on a Form FDA 483, Inspectional Observations, which was issued and discussed with you at the end of the inspection.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions, including, but not limited to, seizure and/or injunction.

Please notify this office within fifteen (15) working days of receiving this letter of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time period within which the corrections will be completed. You may address your reply to Edwin Ramos, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

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